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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|------------------------------|------------------|
| 10/696,797 | 10/30/2003 | Hideo Eda | 43521-1100 | 9441 |
| 21611 | 7590 | 04/25/2006 | EXAMINER BERHANU, ETSUB D | |
| SNELL & WILMER LLP 600 ANTON BOULEVARD SUITE 1400 COSTA MESA, CA 92626 | | | ART UNIT 3768 | PAPER NUMBER |

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/696,797 | EDA ET AL. |
| | Examiner | Art Unit |
| | Etsub D. Berhanu | 3768 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-27 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-27 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 10/30/2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 2/6/04 & 9/12/05.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Specification

2. The disclosure is objected to because of the following informalities: "to measure a degree of acquisition" in line 1 of section [0001] should be omitted; the parenthetical reference of section [0002] is unclear; the phrase "blood amount component" in sections [0009], [0052] and [0053] should read -- blood component amount --; and "leaning" on line 1 of page 11 should read -- learning --.

Appropriate correction is required.

Claim Objections

3. Claims 1, 2-7, 10, 11-16, 19-24 and 27 are objected to because of the following informalities: it is suggested that the phrase "[and] characterized by that" be amended to recite --wherein-- in claims 2, 4-7, 11, 13-16, 21-24 and be omitted in claims 3, 12 and 20 in order to make the claims clear; a colon should be placed after "comprising" on line 1 of claims 1, 10 and 19; --volume-- should be added after "blood" and before "amount" in lines 2, 4 and 7 of claims 1 and 10, lines 3 and 6-7 of claims 9, 18 and 26 and line 1 of claim 27; line 8 of claim 10 improperly renumbers claim 10. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claims 1 and 10 recite the limitation "each work" in line 9. There is insufficient antecedent basis for this limitation in the claims.

7. Claim 1 recites the limitation "the predetermined work" in lines 9-10. There is insufficient antecedent basis for this limitation in the claim.

8. Claim 27 fails to clearly disclose positively recited method steps. It is suggested that the claim be amended to include the phrase "A method for measuring a degree of acquisition comprising:" and further include the terms "measuring", "producing" and "determining".

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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10. Claims 1-3, 5-8, 10-12, 14-17, 19, 20, 22-25 and 27 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 3, 5, 6, 8 and 13 of copending Application No. 2004/0236197. Although the conflicting claims are not identical, they are not patentably distinct from each other because a device and method satisfying the limitations of claims 2, 3, 5, 6, 8 and 13 of the copending application would also meet claims 1-3, 5-8, 10-12, 14-17, 19, 20, 22-25 and 27 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Applicant is advised that should claims 1-9 be found allowable, claims 10-18 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoshi et al. in “Near-Infrared Optical”.

Hoshi et al. discloses a method of detecting brain activation during mental tasks comprising: chronologically measuring the amount of oxyhemoglobin and deoxyhemoglobin in a predetermined measuring region of a brain of a subject with the use of near-infrared spectroscopy, wherein the

predetermined measuring region is the frontal lobe of the subject, and producing diachronic change data of oxyhemoglobin and deoxyhemoglobin (see SUBJECTS AND METHODS section on pages 292-293); and determining a degree of acquisition of work based on the diachronic change data (see second paragraph in right column of page 294 discussing Figure 4).

Hoshi et al. further discloses a device used to implement the method discussed above. The first three paragraphs of the SUBJECTS AND METHODS section disclose a device comprising: a measuring portion that measures the amount of oxyhemoglobin and deoxyhemoglobin in the frontal lobe of a patient, wherein the measuring portion uses near-infrared spectroscopy (right col., page 292); and a calculating portion that calculates relative changes in oxyhemoglobin and deoxyhemoglobin concentrations through time (left col., page 293), displaying the changes in the form of a waveform (Figures 1-6). It is noted that each of the NIRS instruments disclosed in the second paragraph of the SUBJECTS AND METHODS sections is a one-channel instrument. It is further noted that a negative Δ [deoxyhemoglobin] value corresponds to a degree of acquisition, as evidenced by a decrease in [deoxyhemoglobin] values in Figure 4, wherein the subject was able to solve a problem, and an increase in [deoxyhemoglobin] values in Figure 6, wherein the subject was unable to solve a problem.

Regarding claims 9, 18 and 26, Hoshi et al. discloses that the changes in the concentration of oxyhemoglobin and deoxyhemoglobin are calculated based on baseline values, wherein the baseline values are calculated while the subject is in a resting state and in the same position as if they were performing a task, but not conducting the task (last paragraph of SUBJECT AND METHODS section).

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Baird et al. in "Frontal Lobe" discloses the use of near-infrared spectroscopy data to observe a decrease in deoxyhemoglobin concentration during object permanence; Sakatani et al. in "Language-Activated

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Cerebral" discloses results of near-infrared spectroscopy testing that indicates a decrease or no change in deoxyhemoglobin concentration in healthy subjects performing language activities.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Etsub D. Berhanu whose telephone number is 571.272.6563. The examiner can normally be reached on Monday - Friday (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EDB



ERIC F. WINAKUR
PRIMARY EXAMINER